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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/393,590	09/09/1999	ELIZABETH MOYER	00211-US-NEW	2967

21971 7590 05/12/2006

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EXAMINER	
DEVI, SARVAMANGALA J N	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 09/393,590	**Applicant(s)** MOYER ET AL.	
	Examiner S. Devi, Ph.D.	**Art Unit** 1645	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 05 May 2006 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on *05 May 2006*. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☒ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: *None*.
   Claim(s) objected to: *None*.
   Claim(s) rejected: *1-28*.
   Claim(s) withdrawn from consideration: *29-53*.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____
13. ☐ Other: _____.

SD. 05/10/06
S. DEVI, PH.D.
PRIMARY EXAMINER

Continuation of 3. NOTE: The new limitations added to and/or deleted from claims 1 and 16 change the scope of the claims. These newly made amendments were not presented previously and therefore raise new issues at least under 35 U.S.C § 112, requiring further consideration. See below.

The newly added limitations to claim 1: 'for at least 6 months at a temperature between about 10 and 30oC' was not a part of claim 1 previously and therefore requires further consideration and/or search.

The new limitation now added to line 6 of claim 1: 'an excipient protein comprising serum albumin' [Emphasis added] presents new matter and raises a new issue under 35 U.S.C § 112, first paragraph.

The new limitation 'stable' now added to line 1 of claim 1, when read along with the phrase 'capable of being stable' in line 7 of the claim, renders the claim confusing and indefinite.

The newly added limitations to claim 7: 'comprises a buffering component which buffering component' were not previously presented and therefore require further consideration at least under 35 U.S.C § 112, first paragraph.

Claim 16, as amended currently, is inconsistent in the limitations 'serum albumin' (see line 2) and 'human serum albumin' (see last two lines). The two added limitations are not of same scope.

Claim 16, as amended currently, is confusing, incorrect and indefinite with regard to the phrase: 'formulation comprising serum albumin, botulinum toxin formulation .... comprising .... botulinum toxin that is stable in said formulation; and for at least about 6 months ...'. The metes and bounds of this amended claim are indeterminate.

The current deletion of the limitation 'purified' from line 5 of claim 16 broadens the scope of the recited 'botulinum toxin' to encompass isolated and non-isolated botulinum toxin, and raises a new issue that requires further consideration under 35 U.S.C § 102 and/or 103 and/or search.

The new limitations now added to claim 14: 'wherein the stable, ready-to-use liquid formulation comprises 100 mM sodium chloride; 10 mM succinate buffer at a buffered pH of 5.6; 0.5 mg/mL human serum albumin; and botulinum type B present at a concentration of 5,000 + 1000 U/ml' were not previously presented. These limitations change the scope of the claim, thus requiring further consideration under 35 U.S.C § 102 and/or 103 and/or search. The term 'botulinum type B' in the amended claim 14 encompasses a botulinum type B bacterium. It is unclear whether the formulation claimed in claim 14 contains a generic botulinum toxin as recited in the base claim 1, or botulinum type B, i.e., botulinum type B bacterium, as recited in line 4 of claim 14.

The new limitations now added to claim 16: 'and further comprises 100 mM sodium chloride; 10 mM succinate buffer at a buffered pH of 5.6; 0.5 mg/ml human serum albumin and botulinum type B present at a concentration of 5,000 + 1000 U/ml' were not previously presented. These limitations change the scope of the claim, thus requiring further consideration under 35 U.S.C § 102 and/or 103 and/or a further search.

The new limitation 'botulinum type B' now added to the last line of claim 16, when read along with the limitation 'botulinum toxin' in line 5 of the claim, renders the claim confusing and indefinite. The term 'botulinum type B' encompasses botulinum type B bacterium. It is unclear whether the formulation claimed in claim 16 contains a generic botulinum toxin as recited in lines 2 and 5, or botulinum type B, i.e., botulinum type B bacterium, as recited in the last line of the claim..

SD. 05/10/06

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